

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Atty LCM-47-216
Dkt.

GRAHAM et al

C# M#

Serial No. 10/517,256

C/A.U.

1643

Filed: December 7, 2004

Examiner: Rawlings, Stephen L.

Date: April 4, 2008

Title: METHOD OF INHIBITING PROSTATE CANCER CELL PROLIFERATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE/AMENDMENT/LETTER

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

☐ **Correspondence Address Indication Form Attached.****Fees are attached as calculated below:**

Total effective claims after amendment	17	minus highest number			
previously paid for	20	(at least 20) =	0	x \$50.00	\$0.00 (1202)/\$0.00 (2202) \$ 0.00

Independent claims after amendment	5	minus highest number			
previously paid for	5	(at least 3) =	0	x \$210.00	\$0.00 (1201)/\$0.00 (2201) \$ 0.00

If proper multiple dependent claims now added for first time, (ignore improper); add					
					\$370.00 (1203)/\$185.00 (2203) \$ 0.00

Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s)					
					One Month Extension \$120.00 (1251)/\$60.00 (2251)
					Two Month Extensions \$460.00 (1252)/\$230.00 (2252)
					Three Month Extensions \$1050.00 (1253)/\$525.00 (2253)
					Four Month Extensions \$1640.00 (1254)/\$820.00 (2254)
					Five Month Extensions \$2,230.00 (1255)/\$1115.00 (2255) \$ 0.00

Terminal disclaimer enclosed, add					\$130.00 (1814)/ \$65.00 (2814) \$ 0.00
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☐ Applicant claims "small entity" status. ☐ Statement filed herewith

Rule 56 Information Disclosure Statement Filing Fee					\$180.00 (1806) \$ 0.00
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Assignment Recording Fee					\$40.00 (8021) \$ 0.00
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Other:					\$ 0.00
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TOTAL FEE	\$	0.00
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☐ **CREDIT CARD PAYMENT FORM ATTACHED.**

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

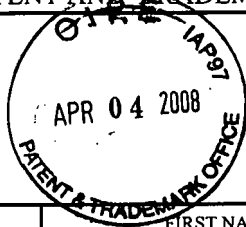
901 North Glebe Road, 11th Floor
Arlington, Virginia 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100
LCM:iff

NIXON & VANDERHYTE P.C.
By Atty: Leonard C. Mitchard, Reg. No. 29,009

Signature: _____



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,256

01/14/2005

Garry George Graham

47-216 *LCM*

7135

23117 7590 04/01/2008
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

RAWLINGS, STEPHEN L

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

04/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Restriction Requirement
1 Month - Non-Compliant 3 SEQ LST DUE
DOCKETED

47-216
4-1-08
May 1, 2008
OCT 1, 2008
fug 1/08



Office Action Summary

Application No.

10/517,256

Applicant(s)

GRAHAM ET AL.

Examiner

Stephen L. Rawlings

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: Notice to Comply; Notice of Non-Compliant Amendment.



DETAILED ACTION

1. The amendment filed December 7, 2004, is acknowledged and has been entered. Claims 3-5, 11, and 15-17 have been amended.
2. The amendment filed January 13, 2006, is acknowledged and has been entered.
3. The amendment filed August 16, 2006, is acknowledged and has been entered in part.
4. Claims 1-17 are pending in the application and are currently subject to restriction.

Response to Amendment

5. The amendment filed on August 16, 2006, is considered non-compliant because it fails to meet the requirements of 37 CFR § 1.121, as amended on June 30, 2003 (see 68 *Fed. Reg.* 38611, Jun. 30, 2003). However, in order to advance prosecution, rather than mailing a Notice of Non-Compliant Amendment, Applicant is advised to correct the following deficiencies in replying to this Office action:

The amendment to the claims is non-compliant because the status identifiers of claims 3-5, 11, and 15-17, which appear in parentheses, do not properly indicate that the claims have been amended; moreover, the claims presented do not show the changes that have already been made in accordance with the amendment filed December 7, 2004.

Applicant is reminded: Only the corrected section(s) of the non-compliant amendment must be resubmitted (in its entirety), e.g., the entire "Amendments to the claims" section of applicant's amendment must be re-submitted. 37 CFR § 1.121(h).

Specification

6. The disclosure is objected to for the following reason: The specification contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). Sequences appearing in the specification and/or drawings must be identified by sequence identifier in accordance with 37 C.F.R. 1.821(d). According to 37 CFR § 1.821(a), an unbranched sequence of four or more specifically identified amino acids or an unbranched sequence of ten or more nucleotides must be identified by sequence identification numbers. See MPEP § 2422.01.

In this instance, the sequence "FSLYK", which is depicted in the paragraph beginning in line 25 at page 32, is not identified by a sequence identification number.

Applicant must provide appropriate amendments to the specification and/or drawings inserting the required sequence identifiers. Sequence identifiers for sequences appearing in the drawings may appear in the drawings or in the brief description of the drawings.

As noted in the attached Notice to Comply, appropriate action correcting this deficiency is required. If necessary to correct the deficiency, Applicant must submit paper and computer-readable copies of a substitute sequence listing, together with an amendment directing its entry into the specification and a statement that the content of both copies are the same and, where applicable, include no new matter.

Election/Restrictions

7. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I. Claim(s) 4, insofar as the claim is drawn to a method for inhibiting or reducing the proliferation of prostate cancer cells, or to a method for treating prostate cancer, said method comprising administering to the cells or to a subject in need of treatment a cPLA₂-α inhibitor.

Group II. Claim(s) 10, insofar as the claim is drawn to a method for inhibiting or reducing the proliferation of prostate cancer cells, or to a method for treating prostate cancer, said method comprising administering to the cells or to a subject in need of treatment a cPLA₂-IIA inhibitor, wherein said cPLA₂-IIA inhibitor is cFLSYK.

Group III. Claim(s) 10, insofar as the claim is drawn to a method for inhibiting or reducing the proliferation of prostate cancer cells, or to a method for treating prostate cancer, said method comprising administering to the cells or to a subject in need of treatment a cPLA₂-IIA inhibitor, wherein said cPLA₂-IIA inhibitor is cFLSYR.

Group IV. Claim(s) 10, insofar as the claim is drawn to a method for inhibiting or reducing the proliferation of prostate cancer cells, or to a method for treating prostate cancer, said method comprising administering to the cells or to a subject in need of treatment a cPLA₂-IIA inhibitor, wherein said cPLA₂-IIA inhibitor is c(2NapA)LS(2NapA)R.

Group V. Claim(s) 11, insofar as the claim is drawn to a method for inhibiting or reducing the proliferation of prostate cancer cells, or to a method for treating prostate cancer, said method comprising administering

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to the cells or to a subject in need of treatment a cPLA₂- α inhibitor and a cPLA₂-IIA inhibitor.

Group VI. Claim(s) 16, insofar as the claim is drawn to a method for detecting prostate cancer or metastases thereof in a subject, said method comprising determining a level of a cPLA₂- α mRNA.

Group VII. Claim(s) 17, insofar as the claim is drawn to a method for detecting prostate cancer or metastases thereof in a subject, said method comprising determining a level of a cPLA₂-IIA mRNA.

Group VIII. Claim(s) 13, insofar as the claim is drawn to a method for detecting prostate cancer or metastases thereof in a subject, said method comprising determining a level of a cPLA₂ polypeptide.

Group IX. Claim(s) 14, drawn to a method for assessing the predisposition of a subject to prostate cancer, said method comprising determining the presence of a polymorphism or an epigenetic change in a cPLA₂ gene of the subject.

8. Claims 1-3 are linking claims, linking the inventions of Groups I-V, whereas claims 5-9 link only the inventions of Groups II, III, and IV. Claims 12 and 15 are linking claims, linking the inventions of Groups VI and VII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional

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application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

9. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions of Groups I-IX appear to be linked by a common concept, or special technical feature, namely contacting prostate cancer cells with a PLA₂ inhibitor, so as to inhibit the proliferation of the cells, as recited in claim 1. However, Herrmann et al. (*Exp. Cell Res.* 1997; **234**: 442-451) teaches contacting prostate cancer cells with a PLA₂ inhibitor (i.e., AACOCF₃), so as to inhibit the proliferation of the cells; see entire document (e.g., page 445, Figure 3). Accordingly, the technical feature that appears to link the inventive concepts of the inventions of Groups I-IX does not constitute a special technical feature as defined by PCT Rule 13.1, as it does not define a contribution over the prior art.

The special technical feature of the invention of Group I is inhibiting or reducing the proliferation of prostate cancer cells, or treating prostate cancer by a process method comprising administering to the cells or to a subject in need of treatment a cPLA₂- α inhibitor.

The special technical feature of the invention of Group II is inhibiting or reducing the proliferation of prostate cancer cells, or treating prostate cancer by a process comprising administering to the cells or to a subject in need of treatment a cPLA₂-IIA inhibitor, wherein said cPLA₂-IIA inhibitor is cFLSYK.

The special technical feature of the invention of Group III is inhibiting or reducing the proliferation of prostate cancer cells, or treating prostate cancer by a process comprising administering to the cells or to a subject in need of treatment a cPLA₂-IIA inhibitor, wherein said cPLA₂-IIA inhibitor is cFLSYR.

The special technical feature of the invention of Group IV is inhibiting or reducing the proliferation of prostate cancer cells, or treating prostate cancer by a process comprising administering to the cells or to a subject in need of treatment a cPLA₂-IIA inhibitor, wherein said cPLA₂-IIA inhibitor is c(2NapA)LS(2NapA)R.

The special technical feature of the invention of Group V is inhibiting or reducing the proliferation of prostate cancer cells, or treating prostate cancer by a process comprising administering to the cells or to a subject in need of treatment a cPLA₂- α inhibitor and a cPLA₂-IIA inhibitor.

The special technical feature of the invention of Group VI is detecting prostate cancer or metastases thereof in a subject by a process comprising determining a level of a cPLA₂- α mRNA.

The special technical feature of the invention of Group VII is detecting prostate cancer or metastases thereof in a subject by a process comprising determining a level of a cPLA₂-IIA mRNA.

The special technical feature of the invention of Group VIII is detecting prostate cancer or metastases thereof in a subject by a process comprising determining a level of a cPLA₂ polypeptide.

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The special technical feature of the invention of Group IX is assessing the predisposition of a subject to prostate cancer by a process comprising determining the presence of a polymorphism or an epigenetic change in a cPLA₂ gene of the subject.

Accordingly, the inventions of Groups I-IX do not share the same or corresponding special technical feature so as to form a single general inventive concept under PCT Rules 13.1 and 13.2.

10. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship

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must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Stephen L. Rawlings/
Stephen L. Rawlings, Ph.D.
Primary Examiner, Art Unit 1643

slr

March 27, 2008



**Notice of Non-Compliance
Amendment (37 CFR 1.121)**

Application No.	Applicant(s)	
10/517,256	GRAHAM ET AL.	
Examiner	Art Unit	
Stephen L. Rawlings	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on 16 August 2006 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
 - ☐ A. Amended paragraph(s) do not include markings.
 - ☐ B. New paragraph(s) should not be underlined.
 - ☐ C. Other _____.
- ☐ 2. Abstract:
 - ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
 - ☐ B. Other _____.
- ☐ 3. Amendments to the drawings:
 - ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
 - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
 - ☐ C. Other _____.
- ☒ 4. Amendments to the claims:
 - ☐ A. A complete listing of all of the claims is not present.
 - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
 - ☒ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
 - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
 - ☐ E. Other: _____.
- ☐ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4):

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.
2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action. If any of above boxes 1. to 4. are checked, the correction required is only the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121.

Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

Failure to timely respond to this notice will result in:

Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

Legal Instruments Examiner (LIE), if applicable

Telephone No.



Notice to Comply

Application No.

10/517,256

Examiner

Stephen L. Rawlings

Applicant(s)

GRAHAM ET AL.

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NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: If necessary to correct the deficiency, Applicant must provide substitute copies of the Sequence Listing, together with an amendment directing its entry and a statement that both copies are the same and include no new matter, as further explained below.

Applicant Must Provide:

- ☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☐ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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Technical Assistance.....703-287-0200

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